**IN THE UNITED STATES DISTRICT COURT**
**FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

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| **UNITED STATES OF AMERICA** | : | **CIVIL ACTION NO. 1:05-CV-2184** |
| ***ex rel.* TED D. KOSENSKE, M.D.,** | : | |
| **Plaintiff** | : | **(Judge Conner)** |
| | : | |
| **v.** | : | |
| | : | |
| **CARLISLE HMA, INC., CARLISLE** | : | |
| **REGIONAL SURGERY CENTER,** | : | |
| **CARLISLE REGIONAL MEDICAL** | : | |
| **CENTER, and HOSPITAL** | : | |
| **MANAGEMENT ASSOCIATES, INC.,** | : | |
| **Defendants** | : | |

**MEMORANDUM**

This is a *qui tam* action filed under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, by relator Ted D. Kosenske ("Kosenske"). Kosenske alleges that defendant Carlisle HMA, Inc. ("Carlisle HMA") and its parent company, defendant Health Management Associates, Inc. ("HMA"),[1] submitted false claims to Medicare

[1]The relator's complaint names the following as defendants: Carlisle HMA, Inc.; the Carlisle Regional Surgery Center ("Surgery Center"); the Carlisle Regional Medical Center ("Medical Center"); and Hospital Management Associates, Inc.

The parties filed a joint stipulation (Doc. 37) indicating that the Surgery Center and the Medical Center "are not separately incorporated legal entities, but rather are names under which Carlisle HMA, Inc. operates." (Doc. 37 ¶ 2.) The joint stipulation also states that the proper name for the party initially identified as *Hospital* Management Associates, Inc. is *Health* Management Associates, Inc. (Id. ¶ 1.) The parties stipulate that the proper caption for this case is *United States of America ex rel. Ted D. Kosenske, M.D. v. Carlisle HMA, Inc. and Health Management Associates, Inc.* (Id. ¶ 3.)

Rule 15(a) of the Federal Rules of Civil Procedure permits a party to amend its pleadings "upon written consent of the adverse party." FED. R. CIV. P. 15(a). Rule 41(a) allows a plaintiff to dismiss an action "by filing a stipulation of dismissal signed by all parties who have appeared in the action." FED. R. CIV. P. 41(a)(1). The court will construe the joint stipulation as an amendment to the caption of the complaint and a dismissal of the Surgery Center and Medical Center. The court will likewise construe the stipulation as conferring the defendants' written consent to the amendment and dismissal for purposes of Rule 15(a) and Rule 41(a). The court will instruct the clerk to modify the docket accordingly.

in violation of kickback and physician referral laws. He predicates this case on the FCA *qui tam* provisions, 31 U.S.C. § 3730(b)-(d), which allow private individuals to bring civil enforcement suits against those who have submitted false claims to the federal government. The FCA grants the government the right to intervene in *qui tam* actions, 31 U.S.C. § 3730(b), but the government has declined to do so in the instant case. (Doc. 5 at 1.)

Presently before the court are the parties' cross-motions for summary judgment (Docs. 43, 45). For the reasons that follow, the defendants' motion (Doc. 43) will be granted, and the plaintiff's motion (Doc. 45) will be denied.[2]

## I. Statement of Facts[3]

This case finds its roots in 1992, when Kosenske and several other anesthesiologists at the Carlisle Hospital[4] in Carlisle, Pennsylvania founded a practice under the professional name of Blue Mountain Anesthesia Associates, P.C. ("BMAA"). (Doc. 44, Ex. B. at 7; Doc. 44, Ex. D at 16; Doc. 48 ¶¶ 1-2; Doc. 54 ¶¶ 1-2.) On December 31 of that year, BMAA entered into a contract ("1992 agreement") with Carlisle Hospital and Health Services ("CHHS"), the predecessor of Carlisle

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[2]In addition to their motion for summary judgment, defendants have filed a motion in limine (Doc. 40) to exclude the testimony and report of relator's expert witness. In light of the court's disposition, it will deny the motion in limine as moot.

[3]The court will present the facts in the light most favorable to the relator. See *infra* Part II.

[4]The name of the hospital has been changed to the Carlisle Regional Medical Center, and new facilities have been developed. The term "hospital" as used herein refers to both entities in succession.

HMA and former operator of the Carlisle Hospital. (Doc. 44, Ex. D at 17; see generally Doc. 44, Ex. A.) The 1992 agreement granted BMAA the exclusive right to provide around-the-clock anesthesiology services at the hospital. (Doc. 44, Ex. A ¶ 1.I, 7.) CHHS also agreed to provide office space, supplies, equipment and personnel for BMAA's use when administering anesthesiology services to patients. (Id. ¶¶ 2.A, 2.B.)

**A. Pain Management Services and the Pain Management Clinic**

Approximately fifteen months after the signing of the 1992 agreement, Kosenske and a hospital nurse began administering pain management services in additional to traditional anesthesia. (Doc. 44, Ex. D at 33; Doc. 48 ¶ 9; Doc. 54 ¶ 9.) BMAA had not widely practiced pain management until that time. (Doc. 44, Ex. D at 33-35; Doc. 48 ¶ 8; Doc. 54 ¶ 8.) Pain management differs from anesthesia in that the latter involves sedation of patients for surgery while the former refers to the treatment of a patient's pain symptoms outside of the surgery context. (Doc. 46 at 3; Doc. 47 ¶¶ 7-8; Doc. 49 ¶¶ 7-8.) Pain management services may, but need not, involve the administration of medication through injection, epidural catheter, or other means to aid the patient in coping with pain. (Doc. 44, Ex. B at 71; Doc. 44, Ex. E at F-11 to -12.) Some cases require only consultation about methods to handle symptoms. (Doc. 44, Ex. B at 71.) One need not be an anesthesiologist to administer pain management, and non-anesthesiologists often perform it in both hospital and office settings. (Doc. 44, Ex. B at 73; Doc. 44, Ex. D at 24, 32; cf. Doc. 44, Ex. E at F-11.)

The 1992 agreement delineates BMAA's anesthesiology duties and responsibilities. (Doc. 44, Ex. A ¶ 1.I.) It describes BMAA's pain management responsibilities less thoroughly. It states that BMAA will use hospital facilities "solely for the practice of anesthesiology and pain management," (see Id. ¶ 1.B), but the agreement never imposes an explicit obligation on BMAA to perform the latter. It does, however, prohibit CHHS from allowing other anesthesiologists to do so unless BMAA "is not qualified or is otherwise unable to render services." (Id. ¶¶ 7, 7.A.)

Kosenske initially shared treatment facilities with the hospital's gastrointestinal endoscopy unit. (Doc. 44, Ex. B at 12; Doc. 44, Ex. D at 33-34.) In 1998, CHHS opened a dedicated pain management clinic at the newly constructed Carlisle Regional Surgery Center ("Surgery Center"), an outpatient surgical and pain treatment facility. (Doc. 44, Ex. D at 36; Doc. 53, Ex. 2 at 63.) CHHS offered BMAA the opportunity to provide exclusive pain management services at the Surgery Center in accordance with the 1992 agreement, and BMAA accepted the invitation. (Doc. 44, Ex. A. ¶ 7.B; Doc. 53, Ex. 2 at 65-66.) CHHS and BMAA never executed a new contract with respect to the pain management clinic. They simply continued to operate under the provisions of the original 1992 agreement. (Doc. 44, Ex. D at 56; Doc. 53, Ex. 2 at 69-70.)

**B. Transfer of the Hospital from CHHS to Carlisle HMA**

In 2001, Carlisle HMA purchased the hospital, Surgery Center, and certain other assets from CHHS. (Doc. 48 ¶ 19; Doc. 53, Ex. 2 at 32; Doc. 54 ¶ 19.) The two entities structured the transaction as an asset purchase rather than a merger, with Carlisle HMA assuming fewer than all of CHHS's assets and liabilities. (Doc. 48 ¶ 19; Doc. 53, Ex. 2 at 32; Doc. 54 ¶ 19.) Medicare regulations allowed Carlisle HMA to continue to use CHHS's Medicare provider number, but they also required it to accept liability for overpayment of Medicare claims made to CHHS.[5] (See generally

[5]Defendants have filed a motion to supplement the record (Doc. 63) with evidence that Carlisle HMA submitted Medicare claims using the provider number originally assigned to the Carlisle Hospital under CHHS ownership. The motion includes an affidavit of HMA vice president Kenneth M. Koopman, cost reports of Carlisle Hospital both before and after the asset purchase, and selected portions of the Medicare Provider Enrollment Application ("Enrollment Application") completed by Carlisle HMA to transfer Carlisle Hospital's Medicare provider number. Kosenske objects to the motion on the ground that defendants possessed these documents prior to filing their motion for summary judgment but failed to place them on the record. (Doc. 66 at 3 n.1.) Further, Kosenske contends that the documents are irrelevant because they do not specifically address whether the 1992 agreement was transferred to Carlisle HMA. (Id. at 7-8.) He also objects to the Enrollment Application excerpts proffered by defendants because they are incomplete, and he has attached a full version to his brief. (Id. at 2.) However, he does not object to supplementing the record with the complete copy. (Id. at 11.)

The court has discretion to grant motions to supplement the record. See Edwards v. Pa. Tpk. Comm'n, 80 F. App'x 261, 265 (3d Cir. 2003) (reviewing district court's grant of motion to supplement the record for abuse of discretion); Dunn v. Gannett N.Y. Newspapers, Inc., 833 F.2d 446, 455 (3d Cir. 1987) (same); cf. FED. R. EVID. 102 (noting that evidentiary issues must be handled in a manner that preserves fairness of proceeding and promotes truth). During oral argument, the parties debated the issue of whether Carlisle HMA is a successor to CHHS under the 1992 agreement. The supplemental evidence demonstrates continuity between the billing practices and Medicare liabilities of the two entities. It is therefore relevant to Carlisle HMA's status as a successor to CHHS under the 1992 agreement.

Doc. 63-4.) After the asset purchase, HMA, the parent company of Carlisle HMA, installed a new management team at the Carlisle Hospital. These executives, who remained on HMA's payroll, controlled the actions of Carlisle HMA and oversaw its compliance with Medicare regulations. (Doc. 53 at 20; Doc. 53, Ex. 2 at 9-10; Doc. 53, Ex. 10 at 6; Doc. 53, Ex. 11 at 11-12.)

CHHS did not execute a formal written assignment of its contractual rights and obligations under the 1992 agreement for the benefit of Carlisle HMA. Nevertheless, after the sale, Carlisle HMA and BMAA conducted their relationship as if the agreement remained in effect. (Doc. 53, Ex. 2 at 34; Doc. 53, Ex. 6 at 34.) Kosenske continued his association with BMAA until 2005, when he left to open an independent pain management practice. (Doc. 44, Ex. B. at 41.) His current professional practice actively competes with Carlisle HMA's pain management clinic. (Doc. 1 ¶ 134; Doc 16. ¶ 134.)

BMAA has never reimbursed CHHS, Carlisle HMA, or HMA for the rental of office space, nor was it obligated to do so under the 1992 agreement. (Doc. 44, Ex. B at 22-23, 34-35; Doc. 47 ¶ 25; Doc. 49 ¶ 25.) It did not pay compensation for its exclusive provider status or for the cost of hospital equipment, personnel, or

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Consideration of the supplemental evidence will allow the court to rule on the pending motions with the benefit of a record that fully represents the nature of the relationship between Carlisle HMA and CHHS. In fairness to all parties, the court concludes that the record should include the entire Enrollment Application. Therefore, it will construe the defendants' motion as a request to supplement the record with the complete Application, and the motion will be granted as so construed.

supplies. (Doc. 47 ¶ 25; Doc. 49 ¶ 25.) Nor has CHHS, Carlisle HMA, or HMA ever compensated BMAA for the anesthesiology and pain management services provided at Carlisle Hospital and the Surgery Center.[6] (Doc. 53, Ex. 6 at 37-38.) Rather, BMAA and Carlisle HMA (and previously CHHS) each submitted claims directly to Medicare and other third-party payors for their respective professional and facilities costs. (Doc. 47 ¶ 29; Doc. 49 ¶ 29; Doc. 53, Ex. 2 at 143; see also Doc. 46-3 col. C; Doc. 46-4 col C.) In the circumstances of the present case, Medicare regulations allow Carlisle HMA and BMAA to segregate their billing into separate components. (Doc. 46 at 23 n.2; MSJ Hr'g Tr. 6-7, Oct. 2, 2007.) BMAA physicians submitted claims under this billing arrangement for the professional services they provided, and Carlisle HMA submitted separate claims for the cost of maintaining the facilities used by the physicians in rendering treatment. (Doc. 48 ¶ 17; Doc. 54 ¶ 17; Doc. 53, Ex. 2 at 150-51; Hr'g Tr. 25.)

[6]Howard Alster, a member of BMAA, receives compensation in the amount of $2,000 per year for serving as chief of the anesthesiology department at the hospital. (Doc. 44, Ex. D at 98.) His deposition testimony indicates that this stipend is paid from dues submitted by the medical staff to retain staff privileges at the hospital, but the record is unclear whether defendants have possession of these dues. (Id. at 98-99.) Relator also testified at his deposition that Alster receives compensation in his role as head of an entity called CHCA, which is "a joint venture between the doctors and HMA." (Doc. 44, Ex. B at 82.) The record is also unclear whether defendants pay this compensation or whether it flows from another source. Regardless of the origin of these monies, the record contains no indication that they compensate Alster for rendering anesthesiology or pain management services to patients.

**C. Relator's Contentions and Procedural History**

The crux of this suit involves Carlisle HMA's alleged non-compliance with the Stark Act, 42 U.S.C. § 1395nn, and Anti-Kickback Act, 42 U.S.C. § 1320a-7b, when submitting its claims for facilities costs to Medicare. These statutes prohibit a health care provider from paying physicians any form of compensation to induce them to refer patients to the provider. They also restrict a physician's ability to own a financial stake in a health care entity to which the physician refers patients. If a health care entity submits a claim to Medicare which derives from a prohibited referral source, it becomes a false claim to which FCA liability may attach. See United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 243 (3d Cir. 2004) (reversing district court dismissal of action under FCA because allegations that defendant violated Stark and Anti-Kickback Acts were sufficient to state claim under it).

In the instant case, Kosenske alleges that BMAA physicians have a financial relationship with Carlisle HMA because it provides them with office space, supplies, equipment, personnel and other benefits without charge. (Doc. 46 at 13-21; Doc. 53 at 1.) Kosenske submits that these benefits constitute compensation given to induce referrals of patients from the pain management clinic to Carlisle HMA. The Stark and Anti-Kickback Acts allegedly prohibit Carlisle HMA from submitting claims for pain management services ordered by BMAA. (Doc. 46 at 28-29.) Kosenske alleges that Carlisle HMA nevertheless submitted numerous such claims, implicating "false claims" under the FCA. (Doc. 53 at 20-21.) HMA never directly

submitted claims to Medicare; however, Kosenske contends that it controlled the actions of Carlisle HMA, including the subsidiary's billing practices. (Id.)

The parties have filed cross-motions for summary judgment on the issue of the defendants' compliance with the Stark Act and the Anti-Kickback Act. If the court finds a violation of either of these statutes, the parties also seek summary judgment on the issue of the defendants' liability under the FCA. The parties have fully briefed these matters, and the court heard oral argument on October 2, 2007.

## II. Standard of Review

Through summary judgment the court may dispose of those claims that do not present a "genuine issue as to any material fact," and for which a jury trial would be an empty and unnecessary formality. See FED. R. CIV. P. 56(c). It places the burden on the non-moving party to come forth with "affirmative evidence, beyond the allegations of the pleadings," in support of its right to relief. Pappas v. City of Lebanon, 331 F. Supp. 2d 311, 315 (M.D. Pa. 2004); FED. R. CIV. P. 56(e); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). This evidence must be adequate, as a matter of law, to sustain a judgment in favor of the non-moving party on the claims. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250-57 (1986); Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587-89 (1986); see also FED. R. CIV. P. 56(c), (e). Only if this threshold is met may the cause of action proceed. Pappas, 331 F. Supp. 2d at 315.

The court is permitted to resolve cross-motions for summary judgment concurrently. Cf. Assicurazioni Generali, S.P.A. v. Pub. Svc. Mut. Ins. Co., 77 F.3d

731, 733 & n.2 (3d Cir. 1996) (observing that district court may dispose of case through cross-motions for summary judgment); see also 10A CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 2720 (3d ed. 1998). When doing so, the court is bound to view the evidence in the light most favorable to the non-moving party with respect to each motion. FED. R. CIV. P. 56; United States v. Hall, 730 F. Supp. 646, 648 (M.D. Pa.1990).

## III. Discussion

Kosenske alleges that defendants submitted claims to Medicare in violation of the Stark Act, 42 U.S.C. § 1395nn, and the Anti-Kickback Act, 42 U.S.C. § 1320a-7b. Both statutes prohibit a health care entity from submitting to Medicare claims that derive from referrals ordered by physicians who receive compensation from the entity. See 42 U.S.C. §§ 1395nn(a); 1320a-7b(b). If the entity has paid compensation to a physician, the entity may submit claims connected to referrals made by the physician only if one of several exceptions to each statute applies. See generally id. § 1395nn(c)-(e) (listing statutory exceptions to the Stark Act); 42 C.F.R. § 411.357 (listing regulatory exceptions to the Stark Act, which provide guidance about application of exceptions listed in statute); 42 C.F.R. § 1001.952 (creating exceptions to Anti-Kickback Act).

A claim knowingly made in violation of either statute constitutes a "false claim" submitted to the federal government and is prohibited by the FCA. United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 243 (3d Cir. 2004); United States v. Rogan, 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006) ("The submission of

[claims] in violation of the Stark Statute constitutes a violation of the FCA."); United States ex rel. Barrett v. Columbia/HCA Healthcare Corp., 251 F. Supp. 2d 28, 32 (D.D.C. 2003) (holding that violation of Anti-Kickback Act implicates FCA liability). As a practical matter, the Stark and Anti-Kickback Acts govern the substantive analysis of Kosenske's allegations. A determination that defendants complied with the Stark and Anti-Kickback Acts necessarily resolves Kosenske's FCA claim in their favor.

**A. The Policies of the Stark and Anti-Kickback Acts**

The Stark and Anti-Kickback Acts ensure the quality of patient care and deter abuse of federal health care programs by proscribing certain conflicts of interest that arise when third-party payors cover the cost of treatment. The Stark Act prevents a physician's personal financial interests from influencing the type and quality of care that patients receive. See Joan H. Krause, A Conceptual Model of Health Care Fraud Enforcement, 12 J.L. & POL'Y 55, 77 (2003) (observing that the Stark Act was "designed to prohibit the referral of Medicare and Medicaid patients to health care providers with whom the referring physician has a financial relationship."). Congress enacted it in the late 1980s in response to studies showing an increase in physician referrals to laboratories when the physician owned an interest in the laboratory to which the referral was made. See id.; accord Physician Ownership of, and Referrals to, Health Care Entities that Furnish Clinical Laboratory Services, 57 Fed. Reg. 8588, 8589 (Mar. 11, 1992). The Act prohibits so-called "self-referrals" in which a physician orders a medically unnecessary

treatment solely because of his or her financial interest in the entity providing that treatment. See McDonnell v. Cardiothoracic & Vascular Surgical Assocs., No. C2-03-0079, 2004 WL 3733404, at *9 (S.D. Ohio Aug. 3, 2004) ("Congress enacted Stark to address the strain placed on the Medicare Trust fund by the overutilization of certain medical services by physicians who, for their own financial gain rather than their patients' medical needs, referred patients to entities in which the physicians held a financial interest."); William M. Sage, Some Principles Require Principals: Why Banning "Conflicts of Interest" Won't Sold Incentive Problems in Biomedical Research, 85 TEX. L. REV. 1413, 1459 n.154 (2007) (stating that the primary purpose of the Stark Act was to ensure financial stability of Medicare and Medicaid against physician self-referrals); Jo-Ellyn Sakowitz Klein, The Stark Laws: Conquering Physician Conflicts of Interest?, 87 GEO. L.J. 499, 506 (1998) (recounting studies published at the time of the Stark Act's passage that found physicians were substantially more likely to refer patients for laboratory tests if the physicians owned a stake in the laboratory to which they referred the patients). Initially limited to laboratory referrals, the Stark Act has been amended to cover a variety of medical services, including inpatient and outpatient hospital services such as anesthesiology and pain management. See Maria A. Morrison, An Analysis of the Stark II Proposed Rule, 67 UMKC L. REV. 613, 613, 619 (1999); see also 42 U.S.C. § 1395nn(a), (h)(6)(K) (prohibiting health care entities from submitting claims for outpatient hospital services to Medicare if those claims derive from self-referrals);

(Doc. 53, Ex. 2 at 72-74 (stating that Carlisle HMA submitted Medicare claims for services provided at pain management clinic as outpatient hospital services)).

The Anti-Kickback Act reinforces the policies underlying the Stark Act through criminal sanctions. It prevents "inappropriate financial considerations from influencing the amount, type, cost, or selection of the provider of medical care received by a federal health care program beneficiary." Thomas N. Bulleit, Jr. & Joan H. Krause, Kickbacks, Courtesies, or Cost-Effectiveness? Application of the Medicare Antikickback Law to the Marketing and Promotional Practices of Drug and Medical Device Manufacturers, 54 FOOD & DRUG L.J. 279, 282 (1999). Its anti-referral provisions bolster those of the Stark Act, prohibiting individuals and entities from "knowingly and willfully solicit[ing] or receiv[ing] any remuneration . . . in return for referring an individual . . . for . . . any item for service" if a claim will be submitted to Medicare. See 42 U.S.C. § 1320a-7b(b)(1)(A). By criminalizing self-referrals committed knowingly, the Act further discourages financial relationships between doctors and health care entities from metamorphosing into personal financial gains at the expense of patients and federal health programs. See Krause, supra, at 68 ("At core [sic], the statute seeks to limit the influence of financial incentives over health care decisions, demanding that such decisions be made solely on the basis of which products and services will best serve the interests of the patient."); Anne W. Morrison, An Analysis of Anti-Kickback and Self-Referral Law in Modern Health Care, 21 J. LEGAL MED. 351, 361-70 (2000) (describing types of kickbacks outlawed by the Anti-Kickback Act).

Despite the conflict-of-interest concerns underlying these Acts, Congress also recognized that certain business relationships between physicians and health care entities are both cost effective and beneficial to patient care. Physicians often find it efficient to refer patients to the health care entities that employ them, rent office space to them, or have some other type of economic relationship with them. These referrals benefit patients' treatment by giving them convenient access to essential services. Both statutes feature exceptions allowing physicians to refer patients to health care entities when those referrals do not implicate the concerns underlying the Stark or Anti-Kickback Acts.

### B. The Stark Act

Evaluation of this case under the Stark Act requires two inquiries. The court must determine whether a financial relationship exists between BMAA and defendants that triggers Stark Act prohibitions. If a financial relationship exists, the court must determine whether Carlisle HMA and HMA meet the requirements of a statutory exception to the Act.

#### 1. Existence of a Financial Relationship and Stark Act Prohibitions

As previously stated, the Stark Act prohibits a physician from referring patients to a health care entity with which the physician has a "financial

relationship" for services[7] covered by Medicare or other federal health care programs. See 42 U.S.C. § 1395nn(a)(1). A "financial relationship" exists between a physician and a health care entity if the two have a "compensation arrangement."[8] See id. § 1395nn(a)(2)(B). A compensation arrangement is "any arrangement involving any remuneration between a physician . . . and an entity . . . [either] directly or indirectly, overtly or covertly, in cash or in kind." Id. § 1395nn(h)(1)(A)-(B). Remuneration includes cash as well as in-kind transfers such as office space, equipment, computer systems, and other benefits passing between an entity and a physician for a cost other than fair market value. See, e.g., United States ex rel. Roberts v. Aging Care Home Health Inc., 474 F. Supp. 2d 810, 817 (W.D. La. 2007) (holding that, absent statutory or regulatory exception, existence of remuneration creates a financial relationship subject to Stark Act); United States v. Capital Group Health Svcs., Inc., No. 4:02-CV-389, 2005 WL 1364619, at *6 (N.D. Fla. June 7, 2005) (observing that remuneration may include in-kind benefits such as "above market consulting fees or rental payments that are above-market or unsupported by a

[7]The statute applies to "designated health services" enumerated in the statute, including inpatient and outpatient hospital services. 42 U.S.C. § 1395nn(h)(6)(K). The pain management services at issue in the present case qualify as outpatient hospital services. (Doc. 47 ¶ 29; Doc. 49 ¶ 29; Doc. 53, Ex. 2 at 141-44; see also Doc. 46-3 col. D; Doc. 46-4 col D.)

[8]A financial relationship also exists if the physician holds an ownership or investment interest in the entity to which the patient is referred. 42 U.S.C. § 1395nn(a)(2)(A). In the instant case, the relator does not allege that BMAA held any such interest in Carlisle HMA and relies exclusively on a compensation arrangement to establish a financial relationship. (See, e.g., Doc. 46 at 13-14.)

written lease" in addition to direct monetary payments); Perales, 243 F. Supp. 2d at 848 (reiterating that any form of remuneration will implicate prohibitions of Stark Act). Hence, if a health care entity pays any form of remuneration to a physician, a compensation arrangement exists between them, resulting in a prohibition of physician referrals to the entity. See id. § 1395nn(a)(2)(B), (h)(1)(B); accord United States ex rel. Perales v. St. Margaret's Hosp., 243 F. Supp. 2d 843, 848 (describing application of statute). Any "request by a physician for an item or service" qualifies as a referral. Id. § 1395nn(h)(5)(A).

In the case *sub judice*, BMAA received numerous benefits as a result of its relationship with CHHS and, later, Carlisle HMA. Under the 1992 agreement, BMAA received the right to provide all anesthesia services at the Carlisle Hospital in perpetuity. (Doc. 44, Ex. A ¶¶ 7, 13; Doc. 44, Ex. D at 32-33, 47-48; Doc. 53, Ex. 2 at 126-27.) The agreement also granted it the right to provide exclusive anesthesiology and pain management services at subsequently developed facilities such as the Surgery Center. (Doc. 44, Ex. A ¶¶ 7.B.) It guaranteed BMAA office space, medical equipment, and clerical personnel without charge. (Doc. 44, Ex. A ¶¶ 1.B, 2.) When CHHS opened the pain clinic, BMAA received similar benefits at that location. (Doc. 44, Ex. A ¶ 7.B; Doc. 44, Ex. D at 53-55.)

Clearly, these benefits constitute remuneration for purposes of the Stark Act.[9] This remuneration establishes a compensation arrangement and financial relationship between BMAA and Carlisle HMA. BMAA ordered numerous pain management services that constitute referrals, and Carlisle HMA submitted claims to Medicare based upon these services. (Doc. 47 ¶ 29; Doc. 49 ¶ 29; Doc. 53, Ex. 2 at 143; see also Doc. 46-3 col. C; Doc. 46-4 col C.) Hence, the Stark Act prohibitions are implicated. The court must therefore determine whether any of the statutory or regulatory exceptions apply.

**2. The Exception for Personal Service Arrangements**

The Stark Act and its accompanying regulations include exceptions permitting physicians and health care entities to conduct referrals that would otherwise be prohibited. When a financial relationship exists, the defendant incurs the burden of demonstrating the applicability of an exception. See Rogan, 459 F. Supp. 2d at 716 ("Once the [relator] has demonstrated proof of each element of a violation of the . . . Stark Statute[], the burden shifts to the defendant to establish

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[9]Kosenske also contends that BMAA's payments from Medicare, Medicaid, and other third-party payors constitute remuneration. (Doc. 46 at 22.) In support of this argument, relator cites a regulatory safe-harbor under the Anti-Kickback Act. (See Doc. 46 at 22-24 (citing 42 C.F.R. § 1001.952(s)(4)). This provision authorizes patient referral for specialty treatment with the understanding that the specialist will "return" the patient to the original physician. However, the referral must meet certain conditions, including: "[T]he only exchange of value between the parties is the remuneration the parties receive directly from third-party payors or the patient." 42 C.F.R. § 1001.952(s)(4). Kosenske argues that even the "expectation of compensation" from third party payors constitutes remuneration. (Id. at 24.)

Having found that Carlisle HMA provided remuneration to BMAA in the form of office space, equipment, supplies, and personnel, the court need not decide whether payment from third-party payors or the expectation of payment constitutes remuneration for purposes of the Stark Act. However, the court would be remiss if it did not express its doubts as to the merits of this attenuated argument.

that his conduct was protected by a safe harbor or exception . . . ."). In the instant case, Carlisle HMA and HMA contend that their relationship with BMAA falls within the ambit of the personal service exception, 42 U.S.C. § 1395nn(e)(3)(A); 42 C.F.R. 411.357(d). This section exempts compensation arrangements from the Stark Act "if the physician's only financial interest in the [entity] is receipt of agreed-upon compensation at or below 'fair market value' for 'reasonable and necessary' services." Renal Physicians Ass'n v. U.S. Dep't of Health and Human Svcs., 489 F.3d 1267, 1269 (D.C. Cir. 2007). Specifically, the exception will apply if:

> (i) the arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement,
>
> (ii) the arrangement covers all of the services to be provided by the physician . . . to the entity,
>
> (iii) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement,
>
> (iv) the term of the arrangement is for at least 1 year,
>
> (v) the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and . . . is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties, [and]

> (vi) the services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates any State or Federal law. . . .

42 U.S.C. 1395nn(e)(3)(A);[10] see also 42 C.F.R. § 411.357(d)(1).

**a. Existence of a Written Agreement**

The first requirement of the personal service exception is a written document signed by the parties and specifying the services to be provided. See 42 U.S.C. § 1395nn(e)(3)(A)(I); see also 42 C.F.R. § 411.357(d)(1)(I). In the instant case, the 1992 agreement signed by BMAA and CHHS is the only writing that could potentially satisfy this requirement.

The 1992 agreement, provides, in pertinent part:

> The right [sic] and obligations of the Hospital hereunder shall insure [sic] to the benefit of and be binding upon the *successors and assigns* of the Hospital. Neither party hereto shall assign its rights or obligations without the other party's written consent.

(Doc. 44, Ex. A ¶ 17 (emphasis added)).

To determine whether the agreement satisfies the first element of the personal service exception, the court must examine whether Carlisle HMA qualifies

[10]The statute contains one additional provision mandating that the agreement "meet[] such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse." 42 U.S.C. § 1395nn(e)(3)(A)(vii). The Department of Health and Human Services has not promulgated additional requirements for personal service agreements. Regulations interpreting the personal service exception simply restate the elements prescribed by the statute and explain the application of certain elements to specific situations not relevant to the present case. See 42 C.F.R. § 411.357(d)(1).

as a successor or assign of CHHS.[11] The construction of a contract term is a question of law, and the court must determine the parties' intended construction by evaluating the instrument in its entirety. See Kalian at Pocono's, LLC v. Saw Creek Estates Cmty. Ass'n, 275 F. Supp. 2d 578, 593 (M.D. Pa. 2003); Murphy v. Duquesne Univ. of the Holy Ghost, 777 A.2d 418, 429 (Pa. 2001). A contract term must not be analyzed in a vacuum but rather evaluated as "applied to a particular set of facts." Kalian, 275 F. Supp. 2d at 594; Murphy, 777 A.2d at 430; RESPA v. Skillman, 768 A.2d 335, 340 (Pa. Super Ct. 2001).

Evaluating the 1992 agreement's succession and assignment clause in the factual context of this case, the court observes that Carlisle HMA's conduct is entirely consistent with an intent to succeed to CHHS's interest under the contract. After Carlisle HMA purchased the assets of CHHS in 2001, it continued to operate the Carlisle Hospital. It filed change-of-ownership documentation with the Department of Health and Human Services in which it agreed to assume liability for Medicare overpayments made during the period of CHHS's ownership.[12]

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[11]The 1992 agreement provides that Pennsylvania law will govern its interpretation, and neither party contests the application of Pennsylvania law. (Id. ¶ 15.) Hence, the court will apply Pennsylvania law to determine Carlisle HMA's status under the agreement.

[12]Ostensibly, there was no indication of Medicare overpayments at the time Carlisle HMA agreed to assume this obligation. (Doc. 66-2 ¶ 3.B.1). Nevertheless, Carlisle HMA's assumption of liability rendered it accountable for subsequently discovered overpayments that were unknown at the time of the asset purchase. Carlisle HMA's willingness to assume this liability clearly indicates its intent to succeed to the medical services business of CHHS, subject to the terms and conditions of the 1992 agreement.

(Doc. 66-2 ¶ 15.A.5.) It also submitted Medicare claims utilizing the provider number previously used by CHHS.[13] (Compare Doc. 63-4, Ex. 1, with Doc. 63-4, Ex. 2.)

When Carlisle HMA assumed ownership of the Carlisle Hospital, BMAA provided anesthesiology and pain management services to Carlisle HMA just as it had to CHHS. No BMAA physician objected to this arrangement at the time of the asset purchase, and BMAA interacted with Carlisle HMA as if the 1992 agreement remained in full force and effect. Even Kosenske continued to provide anesthesiology and pain management services to Carlisle HMA under the 1992 agreement for at least two years before leaving BMAA to establish his own practice. The record contains no indication that CHHS, the original party, ever attempted to assert rights thereunder after the asset purchase was completed. The court concludes that the actions of BMAA, CHHS, and Carlisle HMA clearly and

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[13]Medicare assigns a unique provider number to each provider eligible to submit claims. See 42 C.F.R. § 424.505. When ownership of a provider changes, both the former owner and the purchaser must submit numerous forms to transfer the billing number. See id. § 424.550. This transfer requires the purchaser to assume liability for any overpayment made by Medicare on claims submitted by the previous owner. See id. § 489.18(d) (stating that a Medicare provider agreement transferred from one owner to the next remains subject to all applicable conditions under which it was originally offered); In re Charter Behavioral Health Systems, 45 F. App'x 150, 150 n.1 (3d Cir 2002) (observing that successive owner of a health care facility will remain liable for overpayments to its predecessor if it continues to operate under the predecessor's Medicare provider agreement).

In the case of the Carlisle Hospital, Medicare assigned CHHS provider number 39-0058. (Doc. 63-4, Ex. 1.) Carlisle HMA continued to use this number after the asset purchase. (Doc. 63-4, Ex. 2.) It expressly agreed to assume liability for Medicare overpayments as a condition of the transfer of CHHS's provider number. (Doc. 66-2 ¶ 15.A.5.)

unequivocally demonstrate that all parties intended Carlisle HMA to succeed CHHS under the 1992 agreement for purposes of the Stark Act.[14] Hence, the 1992 agreement fulfills the first requirement of the personal service exception.[15]

**b. Scope of the Agreement**

The second element of the exception requires that the agreement "cover[] all services to be provided by the physician." 42 U.S.C. § 1395nn(e)(3)(A)(ii); see also 42 C.F.R. § 411.357(d)(1)(ii). To benefit from the personal service exception, Carlisle

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[14]Pennsylvania law governing the assumption of liability in cases of corporate asset acquisition fortifies this conclusion. Corporate law generally prevents an acquiring corporation in an asset purchase from becoming a successor to the selling corporation. See Berg v. Chilling Sys. v. Hull Corp., 435 F.3d 455, 464 (3d. Cir. 2006) (reiterating that acquiring corporation typically does not succeed to seller's liabilities). Acquiring corporations will nevertheless become a successors if they expressly or impliedly agree to assume the liabilities of the seller or if they continue to operate the seller's business. See id. (recounting that successor corporation will be bound to predecessor's liabilities if it expressly or impliedly agrees to assume them); Bogart v. Phase II Pasta Machines, Inc., 817 F. Supp. 547, 548 (E.D. Pa. 1993) (observing that a corporation that purchases all assets of another may qualify as a successor of the seller); Dawejko v. Jorgensen Steel Co., 424 A.2d 106, 110 (Pa. Super. Ct. 1981) (holding that a corporation purchasing the assets of another is a successor if it continues the seller's product line). In the case *sub judice*, Carlisle HMA purchased the assets of CHHS, continued to operate its medical facilities, and agreed to assume liability for overpayments CHHS received from Medicare—facts that would tend to show an intent to succeed to CHHS's liabilities.

[15]The parties debate whether Carlisle HMA is also an assign of CHHS. The 1992 agreement requires the written consent of BMAA for assignment, (see Doc. 44, Ex. A ¶ 17), and defendants concede that no written consent was executed. (Doc. 44 at 13.) Relator contends that lack of written consent prevents a transfer of the agreement to Carlisle HMA. The 1992 agreement; however, distinguishes between assignment and succession. Only assignment requires written consent; the contract places no similar restriction on succession. (Doc. 44, Ex. A ¶ 17.) The court's finding that Carlisle HMA qualifies as a successor to CHHS obviates the need to address the issue of whether Carlisle HMA is an assign of CHHS.

HMA must show that the 1992 agreement "covers" the anesthesiology and pain management services provided by BMAA at the hospital and the Surgery Center.

Paragraph 1 of the 1992 agreement, which governs BMAA's obligations, provides in pertinent part:

> 1. Obligations of BMAA. BMAA agrees to provide the following services through its employees during the term of this Agreement.
>
> * * *
>
> B. Medical Practice. BMAA will use the personnel, space, equipment, and supplies provided by the Hospital solely *for the practice of anesthesiology and pain management for the Hospital's patients*.
>
> * * *
>
> I. Coverage. . . . BMAA will render and supervise *all clinical anesthesia services* . . . .

(Doc. 44, Ex. A ¶¶ 1, 1.B (emphases added).) The Hospital's obligations under the agreement correspond to those undertaken by BMAA:

> 2. Obligations of the Hospital. Hospital agrees to provide the following services through its employees during the term of this Agreement:
>
> A. Hospital shall provide, maintain, and make available to BMAA such space, equipment, and supplies and materials as are reasonably necessary and reasonably economical *for BMAA to provide competent and professional anesthesiology services* . . . .
>
> * * *
>
> 7. Exclusivity. . . . [T]he hospital will not otherwise permit any other anesthesiologists not employed by BMAA *to practice anesthesiology or pain management* in the Hospital or at any other facility or location maintained or operated by Hospital.

* * *

> B. In the event that Hospital or CHHS obtains, opens, or operates *another facility or location at which anesthesiology or pain management services are required or offered*, Hospital and CHHS *shall offer BMAA the opportunity to provide exclusive anesthesiology and pain management services as such new facility* or location under the same terms and conditions as provided in this agreement, to the fullest extent that the Hospital and/or CHHS is able to contract with BMAA to provide such services on the same terms and conditions as set forth herein. . . .

(Id. ¶¶ 2, 2.A, 7 (emphases added)).

The court finds that these provisions adequately address all of the anesthesiology and pain management services to be rendered by BMAA at the hospital and the pain management clinic. Paragraphs 1.B and 1.I obligate BMAA to use Carlisle HMA's facilities only for the practice of anesthesiology and pain management. Paragraph 7 prevents Carlisle HMA from engaging non-BMAA anesthesiologists to meet its requirement for those services. Obviously, the agreement makes no mention of the pain management clinic because it did not exist in 1992. Nevertheless, it expressly addresses any future expansion of the pain management practice at the Carlisle Hospital. Paragraph 7.B directly covers the development of new medical facilities and delineates the type of services BMAA will be permitted to provide at those facilities. When the new pain management clinic opened, BMAA provided pain management services consistent with the terms of this paragraph. The court concludes that the 1992 agreement covers all

anesthesiology and pain management services performed by BMAA and satisfies the second element of the personal services exception.[16]

**c. Reasonableness and Necessity**

The third element of the exception prevents the aggregate services from exceeding that which is "reasonable and necessary for the legitimate business purpose of the arrangement." 42 U.S.C. § 1395nn(e)(3)(A)(iii); see also 42 C.F.R. § 411.357(d)(1)(iii). In the instant case, the 1992 agreement covers all anesthesiology and pain management services provided by BMAA, and it prevents Carlisle HMA from procuring those services from other anesthesiologists. (Doc. 44, Ex. A ¶¶ 1.B, 7.) Inasmuch as it is an exclusive contract, it plainly satisfies the reasonableness and necessity criteria of the personal service exception.

**d. Duration**

The exception next mandates that the duration of the arrangement be at least one year. See 42 U.S.C. § 1395nn(e)(3)(A)(iv); see also 42 C.F.R. § 411.357(d)(1)(iv). The 1992 agreement provides for a continuous term terminable only upon the mutual agreement of the parties or for cause. (Doc. 44, Ex. A ¶¶ 13-13.C.) As noted, the parties have abided by the terms of the agreement since its

[16]The post-contract expansion of BMAA's pain management practice does not prevent the 1992 agreement from "cover[ing] all [pain management] services" for Stark purposes. 42 U.S.C. § 1395nn(e)(3)(A)(ii). A contrary conclusion would essentially invalidate provisions for future business growth and require Carlisle HMA and other health care entities to renegotiate personal service contracts whenever they developed new facilities. Applying the Act in such a manner would not further the purpose underlying its passage, to wit: preventing a physician's personal financial interests from influencing the type and quality of patient care.

signing in 1992. Under the rather unique circumstances of this case, the court finds that this contract term is sufficient to fulfill the one-year element of the personal service exception.

**e. Fair Market Value**

The arrangement must also specify the compensation payable under it, which cannot exceed the fair market value of the services actually provided.[17] See 42 U.S.C. § 1395nn(e)(3)(A)(v); see also 42 C.F.R. § 411.357(d)(1)(v). A party may establish fair market value by demonstrating that: (1) it paid the same amount of compensation in a referral transaction that it would have paid in a non-referral transaction; or (2) it paid fair market value based upon any other commercially reasonable criteria. See Renal Physicians Ass'n, 489 F.3d at 1269-70 (citing Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships, 66 Fed. Reg. 856, 944 (Jan. 4, 2001)). This necessitates a fact-intensive inquiry of the circumstances surrounding a particular transaction. See 66 Fed. Reg. at 944 ("The amount of documentation that will be sufficient to confirm fair market value (and general market value) will vary depending on the

[17]The statute defines the term "fair market value" as "the value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee." 42 U.S.C. § 1395nn(h)(3).

circumstances in any given case; that is, there is no rule of thumb that will suffice for all situations.").

Under the 1992 agreement, Carlisle HMA provided BMAA with in-kind remuneration for its services. This remuneration included the exclusive right to practice anesthesiology and pain management at Carlisle HMA facilities, as well as supplies, office space, and personnel. In return, Carlisle HMA gained continuous anesthesiology coverage at its hospital and competent anesthesiologists to staff its pain management clinic.

The mutuality of rights and responsibilities imposed by the 1992 agreement is compelling evidence that the parties engaged in a fair-market-value exchange. The agreement obligated BMAA to provide continuous anesthesia coverage at the hospital; Carlisle HMA received the benefit of having on-call anesthesiologists to treat patients, accessibility critical to emergency treatment. It obligated Carlisle HMA to provide supplies, equipment, personnel, and office space for BMAA's use; BMAA benefitted from access to Carlisle HMA's facilities. It prevented Carlisle HMA from obtaining anesthesiology or pain management services from physicians other than those employed by BMAA; BMAA received the benefit of providing exclusive services to Carlisle HMA. This arrangement represents precisely the type of *quid pro quo* that one would expect in an arm's-length transaction between two entities bargaining for services. By definition, the terms of the contract reflect the fair market value of the benefits conferred on each party. Therefore, the court finds

that agreement complies with the fair market value requirements of the personal service exception.

**f. Violations of Other Applicable Law**

Finally, the exception requires that the arrangement not involve "the counseling or promotion or a business arrangement or other activity that violates any State or Federal law." 42 U.S.C. § 1395nn(e)(3)(A)(vi); see also 42 C.F.R. § 411.357(d)(3)(vi). The record is devoid of any evidence that the arrangement between BMAA and Carlisle HMA violated any law outside of Kosenske's FCA allegations. Accordingly, the court finds that Carlisle HMA has satisfied the final element of the exception for personal service arrangements, and the court will apply the exception to the compensation arrangement in this case.

This result comports with the both the letter and spirit of the Stark Act. Congress designed the Act to prevent physicians from making referrals solely for personal financial gain. The present case does not implicate such concerns. Carlisle HMA retained BMAA as an independent contractor, (see Doc. 44, Ex. A ¶ 5), to provide anesthesia and pain management services at its facilities, using its equipment, aided by its staff. After treating patients, BMAA billed Medicare and other providers for their professional services, and Carlisle HMA billed Medicare for the facilities costs associated with maintaining its buildings, equipment, employees, and supplies. Medicare regulations authorized such a billing system. The benefits each party received under this arrangement did not depend upon the number of patients BMAA treated. BMAA received the same benefits from Carlisle

HMA regardless of the scope and quantity of services rendered. It had no incentive to prescribe services other than those necessary in the course of treatment. In short, the agreement between BMAA and Carlisle HMA presents the paradigm for application of the personal service exception. Therefore, Kosenske's FCA claim must fail to the extent it relies on Stark Act violations for its substance.

**C. The Anti-Kickback Act**

The Anti-Kickback Act, 42 U.S.C. § 1320a-7b criminalizes the knowing and willful payment of remuneration to a physician for referrals of services covered by a federal health care program. See 42 U.S.C. § 1320a-7b(b)(2)(A). Claims submitted in violation of the Act qualify as "false claims" under the FCA, even if no criminal prosecution follows the alleged violation. See United States ex rel. Showell v. Phila. AFL, CIO Hosp. Ass'n, No. CIV.A. 98-1916, 2000 WL 424274, at *7 (E.D. Pa. Apr. 18, 2000); see also United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., 238 F. Supp. 2d 258, 263 (D.D.C. 2002); cf. McNutt ex rel. United States v. Haleyville Med. Supplies, Inc., 423 F.3d 1256, 1260 (11th Cir. 2005) (upholding denial of motion to dismiss under the FCA because government alleged violation of Anti-Kickback Act, which was sufficient to state a claim under the FCA); Schmidt, 386 F.3d at 239-40, 244 (reversing district court's dismissal of an FCA suit based on violations of Stark and Anti-Kickback Acts). The Anti-Kickback Act features regulatory exceptions that remove certain contractual arrangements from its reach. One such exception closely resembles the Stark Act's exception for personal service arrangements:

> Personal services and management contracts. As used in [42 U.S.C. § 1320a-7b], "remuneration" does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met—
>
> (1) The agency agreement is set out in writing and signed by the parties.
>
> (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
>
> (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
>
> (4) The term of the agreement is for not less than one year.
>
> (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
>
> (6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.
>
> (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.
>
> For purposes of [this paragraph], an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

42 C.F.R. § 1001.952(d).

Despite their similarity, compliance with the Stark Act does not immediately import compliance with the Anti-Kickback, and each must be reviewed separately. See OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4863 (Jan. 31, 2005) ("Compliance with a Stark law exception does not immunize an arrangement under the anti-kickback statute."). On the other hand, "compliance with a safe harbor is voluntary[,] and failure to comply with a safe harbor does not mean an arrangement is illegal per se." 70 Fed. Reg. at 4864; accord Feldstein v. Nash Cmty. Health Svcs., 51 F. Supp. 2d 673, 687 (E.D.N.C. 1999) ("[T]he failure to fall within a[n Anti-Kickback] safe harbor does not necessarily mean that the conduct/relationship is prohibited by the . . . statute.").[18]

In the case *sub judice,* Carlisle HMA and HMA assert that they have complied with the Anti-Kickback Act's exception for personal service and management contracts. This exception requires the court to consider as a threshold matter whether an agency relationship exists between defendants and BMAA. See 42 C.F.R. § 1001.952(d) (requiring existence of an agency relationship before parties may invoke exception). The exception defines an agency relationship as one under which an "agent . . . has an agreement to perform services for, or on behalf of, the principal." Id. In the present case, the 1992 agreement expressly authorizes BMAA to provide services on behalf of CHHS and its successor, Carlisle HMA. Thus,

[18]See also Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518, 63545 (Nov. 19, 1999) ("The failure of a particular arrangement to comply with the safe harbor does not determine whether or not the arrangement violates the anti-kickback statute.").

BMAA and Carlisle HMA have an agency relationship which is eligible for the personal service exception.

The remaining language of the personal service exception under the Anti-Kickback Act is nearly identical to its Stark Act equivalent. Only the third element of the Anti-Kickback Act's safe harbor has no Stark kin, and that element, which governs services furnished on a sporadic basis, is inapplicable. Consequently, an analysis of the remaining elements of the Anti-Kickback exception for personal service and management contracts results in a conclusion identical to that reached under the Stark Act's personal service exception. Therefore, the court finds that the 1992 agreement between BMAA and Carlisle HMA meets the requirements of the exception for personal service and management contracts under the Anti-Kickback Act.[19] The court's application of the exception eliminates any need to

[19]As an alternative argument, defendants contend that patients treated by BMAA physicians were *de facto* patients of the hospital, and, therefore, BMAA did not actually make any referrals. (Doc. 44 at 18; MSJ Hr'g Tr. 22-25, Oct. 2, 2007.) In support, defendants observe that Carlisle HMA holds provider-based status under 42 C.F.R. § 413.65 for the pain management clinic. (Hr'g Tr. 23-24.) Providers often utilize this status as a means of developing ancillary facilities and departments to offer additional health care services that complement those already offered by the provider. 42 C.F.R. § 413.65(a)(2). Obtaining this status further benefits providers by allowing them to segregate the professional and technical components of medical bills and to submit them to Medicare separately. (Hr'g Tr. 6-7.) Provider-based status also permits the retention of independent physicians as non-employees. Under this arrangement, the independent physicians submit bills to Medicare for professional services, and the provider submits separate bills for the physical costs of maintaining the facilities used to render those services. (Hr'g Tr. 25.) Attaining provider-based status requires, *inter alia*, the complete integration of the ancillary treatment facilities with the main provider, and patients must have full access to the services of the main provider. See 42 C.F.R. § 413.65(d)(2)(vi); (Hr'g Tr. 23).

address the element of scienter. Kosenske's FCA claim fails to the extent that it relies upon violations of the Anti-Kickback Act.

## IV. Conclusion

Having found that the relationship between BMAA and defendants violated neither the Stark Act nor the Anti-Kickback Act, claims submitted to Medicare for services ordered by BMAA physicians cannot support relator's FCA claims. Accordingly, defendants' motion for summary judgment will be granted. Relator's motion for summary judgment will be denied as moot.

An appropriate order follows.

S/ Christopher C. Conner
CHRISTOPHER C. CONNER
United States District Judge

Dated: November 14, 2007

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In the instant case, it is undisputed that the pain management clinic is completely integrated with other Carlisle HMA facilities in terms of billing and administration as a consequence result of its provider-based status. Patients treated at any integrated facility have access to the full panoply of services provided by defendants, both at the pain clinic and elsewhere. (Doc. 44 at 18; Hr'g Tr. 24.) Thus, when a BMAA physician orders treatment for a pain clinic patient, there is no referral to Carlisle HMA because he or she is already a patient of Carlisle HMA. (Doc. 44 at 18; Hr'g Tr. 24.)

In light of the court's application of the safe harbor provisions of the Stark Act and Anti-Kickback Act, it need not reach this issue. Nevertheless, the court finds defendants' reasoning persuasive and an appropriate, alternative ground for the court's disposition of the matter.

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

| | | |
|---|---|---|
| **UNITED STATES OF AMERICA** *ex rel.* **TED D. KOSENSKE, M.D.,** | : | **CIVIL ACTION NO. 1:05-CV-2184** |
| | : | **(Judge Conner)** |
| **Plaintiff** | : | |
| **v.** | : | |
| **CARLISLE HMA, INC., CARLISLE REGIONAL SURGERY CENTER, CARLISLE REGIONAL MEDICAL CENTER, and HOSPITAL MANAGEMENT ASSOCIATES, INC.,** | : | |
| **Defendants** | : | |

**ORDER**

AND NOW, this 14th day of November, 2007, upon consideration of the parties' joint stipulation regarding issues to be tried (Doc. 37), the cross-motions for summary judgment (Docs. 43, 45), and defendants' motion to supplement the record (Doc. 68), and for the reasons discussed in the accompanying memorandum, it is hereby ORDERED that:

1. The caption of the present action is AMENDED to read: *United States of America ex rel. Ted D. Kosenske, M.D. v. Carlisle HMA, Inc. and Health Management Associates, Inc.* Defendants Carlisle Regional Surgery Center and Carlisle Regional Medical Center are DISMISSED from the action.

2. Defendants' motion to supplement the record (Doc. 63) is CONSTRUED as a request to supplement the record with the affidavit of Kenneth M. Koopman (Doc. 63-4), the cost reports for Carlisle Hospital (Doc. 63-4, Exs. 1 & 2), and the complete Medicare Provider/Supplier Enrollment Application (Doc. 66-2). The motion is GRANTED as so construed.

3. Defendants' motion for summary judgment (Doc. 43) is GRANTED.

4. Defendants' motion in limine (Doc. 40) is DENIED as moot.

5. Relator's motion for summary judgment (Doc. 45) is DENIED.

6. The Clerk of Court is directed to enter JUDGMENT in favor of defendants and against relator on all claims.

7. The Clerk of Court is directed to CLOSE this case.

S/ Christopher C. Conner
CHRISTOPHER C. CONNER
United States District Judge